EXHIBIT 4
DATE 3-23-07
SB 521

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

March 12, 2007

The Honorable Representative Ron Stoker
Chair, House Human Services Committee
Montana House of Representatives
Helena, MT

RE: Senate Bill 521 – An Act Prohibiting the Substitution of Anti-Epilepsy Drugs

Dear Representative Stoker and Honorable Members of the House Human Services Committee,

On behalf of the members of the National Association of Chain Drug Stores (NACDS) operating in Montana, I am writing today to ask your opposition of Senate Bill 521 – An Act Prohibiting the Substitution of Anti-Epilepsy Drugs. Our members in Montana include: Albertsons, Brooks Eckerd, Community Pharmacies, CVS, Hannaford Brothers, Medicine Shoppe, Omnicare, Rite Aid, Sears Holding Company (Kmart), Target, Wal-Mart and Waltz Pharmacy. These members employ over 7,600 Montana residents and contribute over $29 million in state taxes each and every year.

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Introduction
Pharmacist substitution of brand name drugs with FDA-approved, therapeutically equivalent[1] drugs saves money for patients, employers, and payors. It is a legal and well-established practice throughout the country. Prescribers, when issuing prescriptions for their patients, have the authority to indicate whether a pharmacist may engage in generic substitution.

Legislation that would create obstacles to valid existing generic substitution practices for prescription drugs used to treat epilepsy (anticonvulsants) is not good public policy. This bill would prevent pharmacists from engaging in the cost-effective substitution of therapeutically equivalent drugs prescribed to treat epilepsy with generically equivalent alternatives unless the pharmacist first obtains additional consents from both the prescriber and the patient. Such added steps would adversely affect the delivery of patient care and add unnecessary costs because the prescriber has already issued a prescription for the patient.

Prescribers Already Retain the Ultimate Authority
This bill adds redundant and unnecessary health care delivery costs for pharmacists and prescribers. When prescribers issue prescriptions to a patient, they make the

1 http://www.fda.gov/cder/orange/obannual.pdf, page vi. A common misconception is that pharmacists are "generically" substituting a product for a brand name product. Since this language is common, it will be used throughout this Issue Brief, however, it is important to note that pharmacists are engaged in substituting a multi-source product that the FDA has determined to be therapeutically equivalent to the brand name product prescribed.

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determination whether generic substitution is appropriate and indicate that decision on the face of the prescription. There is no benefit or improvement in care achieved by requiring a pharmacist to contact a prescriber to obtain additional consent; doing so only unnecessarily reconfirms the prescriber's earlier decision, and wastes the time and efforts of the prescriber and the pharmacist. The requirements under this legislation would essentially be a duplicate of the intent and consent already given by the prescriber via the original prescription.

This Poor Use of the Prescriber's and Pharmacist's Time Would Have Negative Consequences for Patients

Mandating that a pharmacist obtain additional consent from a prescriber before dispensing an FDA-approved generically equivalent drug would create unnecessary requirements for pharmacists and physicians to perform in their already busy days. The extra time that this new process would require would detract from the ability of both to serve the needs of their patients. Pharmacists would experience severe logistical problems in attempting to obtain additional consent from prescribers. Pharmacists would not be able to reach prescribers who are treating patients, and would have to wait hours or days for a response. The likely result would be massive delays for patients waiting to have their prescriptions filled and added health care costs. Such delays are both an inconvenience to patients and impediments to the timely delivery of patient care. Particularly for epileptics who must strictly comply with their medication regime, delays in drug therapy can have immediate and serious health consequences.

FDA Approves Generic Drugs to Treat Epilepsy

In a 1998 letter to health practitioners from then Associate Commissioner for Health Affairs Dr. Stuart Nightingale, FDA explained its position on therapeutic equivalence between generic and innovator drug products. FDA indicated that generic drugs that have met FDA's rigorous approval process are interchangeable with brand-name drugs under all approved indications and conditions of use. FDA concluded that:

- generically equivalent products do not require any additional clinical tests or examinations by the health care provider when substituted for the brand-name product;
- special precautions are not needed when a formulation and/or a manufacturing change occurs for a drug product so long as the change is approved according to applicable laws and regulations by the FDA;
- as noted in the "Orange Book," in the judgment of the FDA, products evaluated as therapeutically equivalent can be expected to have equivalent clinical effect whether the product is brand name or generic drug product; and,
- it is not necessary for the health care provider to approach any one therapeutic class of drug products differently from any other class, when there has been a determination of therapeutic equivalence by FDA for the drug products under consideration. In making this determination, FDA makes no distinction or exclusions for any specific drug class.

FDA's conclusions are applicable to all generic drugs, including drugs approved to treat epilepsy. As such, no state should enact special requirements for generic substitution that go beyond what FDA has already established is necessary.

Conflicts with Medicaid Laws
This bill proposes requirements that conflict with Medicaid laws relating to generic substitution. Medicaid programs generally require pharmacists to automatically dispense generically equivalent products if prescribers do not expressly indicate on the prescription face that a brand product is medically necessary. In a case where a prescriber makes no indication on a prescription that a brand product is necessary, and the pharmacist is unable to obtain the required additional consent from the prescriber, the pharmacist would be forced to violate either the Medicaid requirement or violate the generic substitution laws relating to dispensing drugs for treatment of epilepsy. Creating a law that would force pharmacists into a Hobson's choice, that would lead them to break another law, is unworkable and poor public policy.

This Proposed Process Creates Barriers to Generic Substitution that Would Ultimately Increase Costs to Patients and the Healthcare System Unnecessarily
If pharmacists are required to obtain additional consent for generic substitution of prescription drugs approved or used to treat epilepsy , it would become a deterrent to generic substitution. Due to the logistical challenges, pharmacists would be forced to fill prescriptions with more expensive brand name products even if the patient prefers to receive the generically equivalent product. The unfortunate result of this scenario is that patients would have no choice other than to pay higher prices for the more expensive brand product.

As you and the committee consider this legislation, Senate Bill 521, I would ask that you give serious consideration to the negative impact this legislation would have in Montana on both clients themselves and the state budget.

If I can answer any questions, or provide you with additional information, please do not hesitate to contact me.

Sincerely,

Lis Houchen

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